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EXAMINER	
VANDERVEGT, FRANCOIS P	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,066	SIMARD ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 29-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 29-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant has amended the specification to correct the priority information.

This application is a continuation of U.S. Application Serial Number 10/005,905; which is a continuation-in-part of U.S. Application Serial Number 09/561,074 and is a continuation-in-part of U.S. Application Serial Number 09/560,465 and is a continuation-in-part of U.S. Application Serial Number 09/561,572 and is a continuation-in-part of U.S. Application Serial Number 09/561,571 and is a continuation-in-part of U.S. Application Serial Number PCT/US01/13806.

Claims 6-28 have been canceled.

New claims 37-42 have been added.

Claims 1-5 and 29-42 are currently pending.

Election/Restrictions

1. Applicant asserted in the response filed April 5, 2004 that claim 1 is a linking claim that links the claims of Groups II and III to Group I. Applicant contended that the "provisional election is made with the understanding that upon allowance of linking claim 1, the restriction between the claims of Group II and Group III shall be withdrawn." It is noted, however, that Applicant has canceled all claims drawn to Groups II and III.

However, Applicant was notified in section 9 of the Restriction Requirement mailed March 5, 2004 regarding rejoinder practice. Specifically, Applicant was advised that, in order to retain the right to rejoinder, the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Applicant was further advised that failure to do so may result in a loss of the right to rejoinder. In canceling the claims drawn to Groups II and III, Applicant has failed to keep the method claims co-pending with the compound claims.

Accordingly, rejoinder of the method claims with compound claims that are ultimately found allowable may not be required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 29, 30, 33-35 and 37-42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zajac et al (145 on form PTO-1449; Int. J. Cancer [1997] 71:491-496).

It was previously stated: "Zajac teaches isolated T cells that recognize the HLA-A2.1-restricted housekeeping epitope consisting of amino acid residues 27-35 of the MelanA tumor-associated antigen from melanoma target cells (Abstract and page 491, first column in particular)[claims 1, 3, 29, 30, 33-35]. Zajac teaches that tumor-infiltrating-lymphocytes (TILs) were isolated from melanoma patients were able to specifically lyse target cells (pages 492-493 and Figure 2 in particular). The TILs qualify as being "isolated from an immunized animal" because they were obtained from melanoma patients and were therefore "immunized" to the antigen by the presence of the tumor in their body [claim 5]. Zajac also teaches that peripheral blood lymphocytes from healthy donors that were primed *in vitro* with the peptide generated cytotoxic T lymphocytes (CTLs) that were able to specifically lyse target cells (pages 492-494 and Figure 3 in particular)[claim 4]. Zajac further teaches specific lysis of the target cells by the HLA-A2.1 restricted T cell lines HBL and D10 (Figures 2 and 3 in particular)[claim 2]. The prior art teaching clearly anticipates the claimed invention."

Applicant's arguments filed September 15. 2004 have been fully considered but they are not persuasive.

Applicant has amended the claims to recite that the T cells of the claimed invention are part of a composition suitable for administration to an animal and that the composition further comprises a pharmaceutically acceptable carrier, adjuvant, diluent or exipient. Applicant argues that the Zajac reference does not anticipate the claims as amended because the in vitro assay composition of Zajac contains components such as EBV-transformed cells and fetal calf serum, which would render the composition unsuitable for administration to animals. While Applicant's arguments might be true of compositions for administration to humans due to regulatory issues, there is no such restriction on giving compositions comprising these elements to non-human experimental animals. The administration of transformed cells or cells grown in FBS-containing media to non-human animals is routine in the art.

Applicant further argues that the Zajac reference does not anticipate claim 42 because Zajac does not teach a second T cell population against a second epitope. This is not convincing because there is no requirement in the claim that the second T cell population or epitope are different from the first. The interpretation that the first and second T cell populations are the same is supported by new claims 38 and 39, which recite that the "first antigen and second antigen are the same" in claim 38 and that the "first target cell and second target cell are the same" in claim 39. If the first and second antigens are the same, then the second "housekeeping epitope" derived therefrom (see claim 37) can also be the same as the first housekeeping epitope.

3. Claims 1-5, 29, 30, 33, 34 and 36-42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kittlesen et al (79 on form PTO-1449; J. Immunol. [1998] 160:2099-2106).

It was previously stated: "Kittlesen teaches isolated T cell lines that recognize the HLA-A1-restricted housekeeping epitope consisting of the amino acid sequence KCDICTDEY of the tyrosinase tumor-associated antigen from melanoma target cells (Abstract and page 2100, first column in particular)[claims 1, 29, 30, 33, 34, 36]. Kittlesen teaches that the tyrosine reactive T cells are obtained from melanoma patients whose tumors express tyrosinase (paragraph bridging pages 2100-2101 in particular) and therefore qualify as being "isolated from an immunized animal" because they were obtained from melanoma patients and were therefore "immunized" to the antigen by the presence of the tumor in their body [claim 5]. Kittlesen further teaches that the T cell lines were enriched in vitro from polyclonal populations [claim 3] obtained from melanoma patients by repeated rounds of stimulation with the peptide (page 2100, first column in particular) [claims 2, 4]. The prior art teaching clearly anticipates the claimed invention."

Applicant has amended the claims to recite that the T cells of the claimed invention are part of a composition suitable for administration to an animal and that the composition further comprises a pharmaceutically acceptable carrier, adjuvant, diluent or exipient. Applicant argues that the Kittlesen reference does not anticipate the claims as amended because the in vitro assay composition of Kittlesen contains components such as EBV-transformed cells and fetal calf serum, which would render the composition unsuitable for administration to animals. While Applicant's arguments might be true of compositions for administration to humans due to regulatory issues, there is no such restriction on giving compositions comprising these elements to non-human experimental animals. The administration of transformed cells or cells grown in FBS-containing media to non-human animals is routine in the art.

Applicant further argues that the Kittlesen reference does not anticipate claim 42 because Kittlesen does not teach a second T cell population against a second epitope. This is not convincing because there is no requirement in the claim that the second T cell population or epitope are different from the first. The interpretation that the first and second T cell populations are the same is supported by new claims 38 and 39, which recite that the "first antigen and second antigen are the same" in claim 38 and that the "first target cell and second target cell are the same" in claim 39. If the first and second antigens are the same, then the second "housekeeping epitope" derived therefrom (see claim 37) can also be the same as the first housekeeping epitope.

4. Claims 1-4, 29-32, 35 and 37-42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Jager et al (75 on form PTO-1449; J. Exp. Med. [1998] 187:265-270).

It was previously stated: "Jager teaches isolated CD4+ T cell lines and an HLA-A2 restricted CTL clonal line that recognize housekeeping epitopes of the NY-ESO-1 cancer-testis tumor-associated antigen (Abstract and page 266, first column in particular)[claims 1-3, 29-32, 35]. Jager teaches that the NY-ESO-1 reactive T cells are obtained from PBL and a needle biopsy from a melanoma patient. Kittlesen further teaches that the T cell lines were enriched in vitro from polyclonal populations [claim 3] obtained from the melanoma patient by repeated rounds of stimulation with the peptide (page 266 in particular) [claims 2, 4]. The prior art teaching clearly anticipates the claimed invention."

Applicant has amended the claims to recite that the T cells of the claimed invention are part of a composition suitable for administration to an animal and that the composition further comprises a pharmaceutically acceptable carrier, adjuvant, diluent or exipient. Applicant argues that the Jager reference does not anticipate the claims as amended because the in vitro assay composition of Jager contains components such as EBV-transformed cells and fetal calf serum, which would render the composition unsuitable for administration to animals. While Applicant's arguments might be true of compositions for administration to humans due to regulatory issues, there is no such restriction on giving compositions comprising these elements to non-human experimental animals. The administration of transformed cells or cells grown in FBS-containing media to non-human animals is routine in the art.

Applicant further argues that the Jager reference does not anticipate claim 42 because Jager does not teach a second T cell population against a second epitope. This is not convincing because there is no requirement in the claim that the second T cell population or epitope are different from the first. The interpretation that the first and second T cell populations are the same is supported by new claims 38 and 39, which recite that the "first antigen and second antigen are the same" in claim 38 and that the "first target cell and second target cell are the same" in claim 39. If the first and second antigens are the same, then the second "housekeeping epitope" derived therefrom (see claim 37) can also be the same as the first housekeeping epitope.

Conclusion

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
June 10, 2004

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
11/24/04